



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

5173 '02 MAY 29 P2:38

MAY 24 2002

Mr. Vijay Kumar  
Co-Owner  
Shanti Herbs  
P.O. Box 74488  
Los Angeles, California 90004

Dear Mr. Kumar:

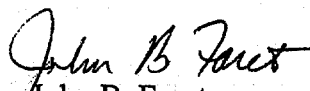
This is in response to your letter of April 28, 2002 to the Food and Drug Administration (FDA) responding to our March 26, 2002 letter concerning the claims being made for the product Gluco Health.

In your letter, you proposed to change your claim to read "Natural balanced sugar regulator blend." Your proposed new claim appears to resolve the issues we raised in our letter and we have no further comment on the claims you intend to make for Gluco Health.

You also stated that you wanted to continue using the labels for this product that contained the claim that was the subject of our previous letter. But, you stated you would use those labels only after you covered the old claim with a sticker containing the new claim. We have no objection to your re-labeling proposal.

Please contact us if we may be of further assistance.

Sincerely,

  
John B. Foret

Director

Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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**Copies:**

**FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300**

**FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200**

**FDA, Los Angeles District Office, Office of Compliance, HFR-PA240**

# SHANTI HERBALS

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Date-04/28/02

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service H F S 810  
200 C Street SW  
Washington, D.C. 20204

Dear Mr. Foret:

In response to your letters dated March 26, 2002 and April 8, 2002 to co-owner Gladys Valencia, if our structure/function claim of our product GLUCO HEALTH is controversial, we will change the claim.

We are a newly formed small company and our funds are limited. We have already printed 10,000 labels and we would like to use those labels by fixing an adhesive sticker over the label claim panel with new wording replacing the old line "helps maintain healthy blood sugar level". Instead of that line we will insert the following wording:


**"Natural balanced sugar regulator blend"**

Another company named HIMALAYA USA, 10440 Westoffice Dr., Houston, TX 77042, has taken the similar label claim **"Nature's balanced sugar regulator formula"**

Please advise us whether the above wording is under compliance and whether it falls under structural/functional claim category. We do not want to take any disease claim. Our labels also contain the following disclaimer: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any Disease"

I await hearing from you.

Sincerely yours,

  
Vijay Kumar  
Co-Owner

cc:

FDA, Center for Drug Evaluation and Research  
Office of Compliance, HFD-300  
FDA, Office of the Associate Commission for Regulatory Affairs,  
Office of Enforcement, HFC-200  
FDA, Los Angeles, District Office, Office of Compliance, HFR-PA240



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

APR - 8 2002

Ms. Gladys Valencia  
Owner  
Shanti Herbs  
P.O. Box 74488  
Los Angeles, California 90004

Dear Ms. Valencia:

This is in response to your letter of December 15, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product Gluco Health uses the claim "helps maintain healthy blood sugar level." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to your claim about control of blood sugar level; that is, a claim that does not establish that the claim is about blood sugar that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

**Page 2 - Ms. Gladys Valencia**

**Please contact us if we may be of further assistance.**

**Sincerely,**



**John B. Foret**

**Director**

**Division of Compliance and Enforcement**

**Office of Nutritional Products, Labeling  
and Dietary Supplements**

**Center for Food Safety  
and Applied Nutrition**

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